NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re Columbia Laboratories, Inc. Securities Litigation	:	Hon. Faith S. Hochberg, U.S.D.J.
	:	Civil Case No. 12-614 (FSH)
THIS DOCUMENT RELATES TO: All Actions	:	**OPINION**
	:	Date: October 21, 2013

HOCHBERG, District Judge:

This matter comes before the Court upon Defendants' motions to dismiss Plaintiffs' Consolidated Second Amended Class Action Complaint [Dkt. No. 74].[1] The Court has reviewed the submissions of the parties and considers the motions on the papers pursuant to Federal Rule of Civil Procedure 78.

I. BACKGROUND[2]

Plaintiffs represent a putative class of purchasers of Columbia Laboratories, Inc. ("Columbia") securities between December 6, 2010 and January 20, 2012 (the "Class Period"). Defendants are two pharmaceutical companies, Columbia Laboratories, Inc. ("Columbia") and Watson Pharmaceuticals, Inc. ("Watson"), and five senior executives of both companies (collectively, the "Defendants").

[1] Defendants Columbia and Watson have filed separate briefing for these motions but their arguments will be analyzed together in this opinion, except where noted.

[2] The following alleged facts have been taken from the Consolidated Second Amended Class Action Complaint [Dkt. No. 74]. For these motions to dismiss, the Court will accept the factual allegations in the Second Amended Complaint as true and construe all facts in Plaintiffs' favor.

In their Consolidated Second Amended Class Action Complaint ("Second Amended Complaint"), Plaintiffs allege that during the Class Period, Defendants misled investors about the results of Columbia's single clinical trial, Study 302, for its drug PROCHIEVE® progesterone vaginal gel 8% ("Prochieve"), and that this violated Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5. Plaintiffs also allege control person liability under Section 20 of the Exchange Act against the five individual defendants.

a. Prochieve NDA

Columbia sought approval from the U.S. Food and Drug Administration ("FDA") through a New Drug Application ("NDA") to use Prochieve to reduce the risk of preterm birth. As part of the NDA, Columbia had to submit data from clinical trial results to show the gel's efficacy. (2d Am. Compl. ¶ 47.) Generally, for an NDA to be approved, data of a drug's safety and efficacy must be supported by at least two trials, and clinical study results are considered statistically significant if they achieve a Confidence Interval level of 95%, or a p-value ≤ 0.05. (2d Am. Compl. ¶¶ 48, 67.) *See Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 592 (D.N.J. 2002) ("The P-value measures the likelihood that one would see the observed association even in the absence of a true association. The lower the p-value, the less likely the observed result is due to chance alone. . . . Traditionally, p-values are termed 'statistically significant' when they are less than 5 percent ($p < 0.05$) and confidence intervals (or 'level of confidence') are set at 95%.").

In 2004, Columbia initiated a clinical study, Study 300, to evaluate the efficacy of the progesterone gel for women with histories of preterm birth. (2d Am. Compl. ¶ 36.) The FDA met with Columbia to discuss the study and advised Columbia that one trial like Study 300, as opposed to two or more trials, "might be adequate" to support the NDA "if it showed a robust

statistically significant reduction in preterm births at less than or equal to 32 weeks gestation . . . ." (2d Am. Compl. ¶ 66.) In April 2004, the FDA clarified that "robust" meant the primary endpoint for a preterm birth indication achieved a p-value ≤ 0.01, or, in other words, a 99% Confidence Interval level or 1% chance of a false positive.[3] (2d Am. Compl. ¶ 66.) In 2007, Study 300 revealed that Prochieve had not reduced preterm births by a statistically significant margin. (2d Am. Compl. ¶ 36.)

However, Columbia discovered during Study 300 that Prochieve was effective in reducing preterm births for women with short cervixes. It sought to submit the results of Study 300 to support an NDA for Prochieve to reduce preterm birth in women with short cervixes, but the FDA told Columbia that approval for this purpose would require at least one more study focusing on this group of women. Columbia thus designed the multinational trial, Study 302, which was conducted between March 2008 and November 2010.[4] (2d Am. Compl. ¶¶ 37-38, 49.)

In February 2011, a pre-NDA meeting was held between Columbia and the FDA where they discussed Study 302 and finalized a Statistical Analysis Plan to ensure that variations in

[3] Plaintiffs characterize this p-value as a requirement instituted by the FDA, while Defendants contend that the FDA was merely offering guidance, specifically guidance for Study 300.

[4] As alleged in the Second Amended Complaint, on March 3, 2010, while Study 302 was ongoing, Columbia entered into a purchase agreement with Watson for later-stage clinical development and commercialization of Prochieve. Pursuant to the agreement, Columbia sold its assets relating to the research and development, regulatory approval, manufacturing, distribution and sales of Prochieve and its other progesterone products for $62 million in cash and debt; Watson also obtained 11.2 million shares of CBRX common stock. Columbia would in turn receive tiered royalties from Watson on sales of Prochieve. (2d Am. Compl. ¶ 39.) Columbia was still financially responsible for the costs of completion of Study 302 and for filing the NDA. Once Columbia met a $7 million cap, further development costs were paid by Watson. (2d Am. Compl. ¶ 40.) Watson also agreed to pay milestone payments to Columbia, contingent upon the p-value of Study 302. (2d Am. Compl. ¶ 41.) On February 10, 2012, Columbia transferred the NDA to Watson. (2d Am. Compl. ¶ 13.)

results across test sites did not indicate localized data issues. (2d Am. Compl. ¶ 80.) Plaintiffs do not allege that the FDA communicated a p-value requirement for approval of the NDA at this time. Study 302 ultimately yielded an overall p-value of 0.022, and a p-value of 0.659 for the U.S. population alone. (2d Am. Compl. ¶¶ 65, 80.) According to the Second Amended Complaint, Study 302 only achieved overall statistical significance at the 95% level by including "suspiciously anomalous results from sites in Belarus and South Africa," countries with purportedly untested regulatory regimes. (2d Am. Compl. ¶ 89.)

Columbia submitted the Prochieve NDA to the FDA on April 26, 2011. Defendants announced on June 27, 2011 that the FDA had accepted the NDA filing for Prochieve. (2d Am. Compl. ¶ 55.) On June 28, 2011, the FDA issued a letter to Defendants indicating that "the discrepancy in efficacy results across U.S. and foreign sites [is] a potential review issue." (2d Am. Compl. ¶ 58.) Over six months later on January 20, 2012, the FDA convened an Advisory Panel that met and voted 13-4 not to recommend approval of Prochieve as a therapy against preterm births.[5] (2d Am. Compl. ¶ 138.) Columbia thereafter announced this result to the public. (2d Am. Compl. ¶ 139.) On February 24, 2012, the FDA notified Watson that it declined to approve the NDA, and on February 27, 2012, Defendants announced this to the public. (2d Am. Compl. ¶¶ 13, 141.)

[5] In the Second Amended Complaint, Plaintiffs also allege that the FDA and Panel members made various statements in pre-meeting Briefing Documents and at the Panel Meeting, including statements that "[Columbia]'s analysis shows marginal overall significance," that "to support drug approval based on a single study, efficacy evidence must be highly statistically persuasive," and that in April 2004, "robust" findings was clarified to mean a p-value of 0.01. (2d Am. Compl. ¶¶ 71-75.) However, aside from the April 2004 communication made with respect to Study 300, the Second Amended Complaint does not allege that the FDA communicated to Defendants a p-value requirement of 0.01 for Study 302.

b. Alleged Misstatements

At issue in this case are several statements that Defendants made during the Class Period in press releases, conference calls, presentations, and the SEC Form 10-k that characterized Study 302 as a success and explained that its "top-line results" were "statistically significant." (2d Am. Compl. ¶¶ 100-103, 107, 109-111, 113-114, 116, 118-119, 121, 124, 127, 129, 131, 134.) Defendants did not make statements about the results on a site-by-site basis. Plaintiffs contend that the p-value of 0.01 identified by the FDA for Study 300 was still the requirement for Study 302 because Study 302 was one trial relating to the same drug and had a similar endpoint, albeit with a different patient population. They assert that Defendants' statements were misleading because Study 302 failed to demonstrate this required robust statistical significance, because Study 302 did not achieve statistical significance for its target U.S. population even at the 95% level, and because Study 302 achieved statistical significance at the 95% level only by including highly discrepant data from Belarus and South Africa. (2d Am. Compl. ¶¶ 104-105, 108, 115, 117, 120, 122, 125.) Plaintiffs also contend that Defendants' statements made after the FDA sent its June 28, 2011 letter (noting possible concern with Study 302) were misleading for failure to disclose existence of the FDA's letter and because Watson had allegedly been preparing its employees for Prochieve's rejection. (2d Am. Compl. ¶¶ 128, 130, 132, 135.)

In the Second Amended Complaint, Plaintiffs further allege that there were two corrective disclosures which unveiled the truth about the p-value requirement and subgroup data: the publication of the FDA's briefing materials on January 17, 2012, and the Advisory Panel's vote not to recommend approval of the Prochieve NDA on January 20, 2012. (2d Am. Compl.

¶¶ 136-140.) According to Plaintiffs, Columbia shares significantly declined in response to these corrective disclosures. (*Id*.)

c. Material Added to the Second Amended Complaint

Plaintiffs' additions and modifications to the Second Amended Complaint can be summarized as follows:

- Plaintiffs allege that David Devoe ("Devoe"), a district sales manager in Watson's Women's Health Division, learned in July 2011 that Prochieve "wasn't going to be approved." (2d Am. Compl. ¶ 8.) They also allege that "[a]s a result Watson's senior managers as early as July 2011 'were already talking about what [they] were going to do' during sales meetings as a result of the likely failure of the PROCHIEVE 8% NDA." (2d Am. Compl. ¶ 8; *see also id*. ¶¶ 59, 128, 130, 132, 135, 151.)

- Plaintiffs allege that "there is little doubt" that Columbia Defendants were also aware of the information that led Watson to conclude that the Prochieve NDA was likely to be rejected. (2d Am. Compl. ¶ 146.)

- Plaintiffs allege that "whereas 'statistical significance' is the generally accepted standard for demonstrating efficacy, the FDA requires a 'statistically very persuasive finding' when a single study trial is submitted in support of an NDA." (2d Am. Compl. ¶ 50.)

- Plaintiffs allege that Defendant Condella failed to disclose that the FDA had previously given Columbia a specific mandate with respect to the 99% threshold for Study 300 in response to the question, "So there was no lower p-value required by the fact that you are doing only one trial here?"[6] (2d Am. Compl. ¶¶ 69-70.) Plaintiffs also allege that it was incumbent upon Defendants to re-inquire with the FDA about the required p-value for Study 302 prior to making announcements about the results of Study 302. Plaintiffs allege that Defendants' failure to do so shows reckless disregard of the truth in disclosures to investors. (2d Am. Compl. ¶ 70.)

- Plaintiffs also state that the following events do not indicate that the FDA found the Study 302 results to be sufficient for approval:

    - The FDA's approval of a statistical analysis plan ("SAP") for Study 302 at a February 2011 meeting with Columbia (2d Am. Compl. ¶ 54)

[6] In response to this question, Defendant Condell stated, "We don't know until we talk to the FDA but I can't tell you what the specific p-value was. All I can say is it was statistically significant." (2d Am. Compl. ¶ 69.)

- The FDA's acceptance of the Prochieve NDA filing[7] (2d Am. Compl. ¶ 56)
- The FDA's decision to convene an Advisory Panel[8] (2d Am. Compl. ¶ 62)
- The acceptance of Study 302 in a medical journal (2d Am. Compl. ¶ 133)

II. STANDARD OF REVIEW

In order to state a claim under Section 10b and SEC Rule 10b-5, a plaintiff must allege that the defendant (1) made a misstatement or an omission of a material fact; (2) with scienter; (3) in connection with the purchase or sale of a security; (4) upon which the plaintiff reasonably relied; and (5) that the plaintiff's reliance was the proximate cause of the injury.[9] *In re IKON Office Solutions, Inc.*, 277 F.3d 658, 666 (3d Cir. 2002); *In re Great Atlantic & Pacific Tea Co., Inc. Sec. Litig.*, 103 F. App'x 465, 468 (3d Cir. 2004) ("*A&P*").

A securities fraud claim is subject to heightened pleading requirements. Under Federal Rule of Civil Procedure 9(b), the circumstances constituting fraud shall be stated with particularity. The Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u, adds a requirement that, with respect to each act or omission alleged to violate the PSLRA, the complaint shall state with particularity the facts (*i.e.*, the who, what, where, when, and how)

[7] The Complaint also alleges that the FDA does not conduct a substantive review of an application at the time it accepts an NDA for filing; rather the goal is to determine whether or not the filing is sufficiently complete to permit substantive review. (2d Am. Compl. ¶ 56.) Plaintiffs also allege that an application is "fileable" when "there are no major omissions of data" or other "facially apparent deficiencies in the submission." (*Id*.)

[8] Plaintiffs allege that FDA regulations provide that an advisory panel should be convened when "there are significant issues regarding safety and/or effectiveness of the drug or biologic," or "the application raises significant public health questions regarding the role of the drug or biologic in the treatment of a disease." (2d Am. Compl. ¶ 62.) The Second Amended Complaint also alleges that the FDA found that the proposed indication (the reduction of preterm birth) addressed "a significant public health problem in the US and globally." (*Id*.)

[9] Control person claims under Section 20(a) are derivative of primary securities violations by the corporate defendant. *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 284 (3d Cir. 2006).

giving rise to a strong inference that the defendant acted with the required state of mind or scienter. *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 252-53 (3d Cir. 2009); *A&P*, 103 F. App'x at 468-69. "Scienter is a mental state embracing intent to deceive, manipulate, or defraud, and requires a knowing or reckless state of mind." *City of Roseville Employees' Retirement System v. Horizon Lines, Inc.*, 442 F. App'x 672, 674 (3d Cir. 2011) (quoting *Avaya*, 564 F.3d at 252). The standard for recklessness is high: "a reckless statement is one involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Id*. at 674-75.

In determining whether a plaintiff has properly pled scienter under the PSLRA, a court must weigh "plausible opposing inferences." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007). A securities fraud complaint will survive only where the inference of scienter raised by the alleged facts, taken collectively, is more than merely plausible or reasonable; it must be cogent and at least as compelling as any opposing inference of non-fraudulent intent one could rationally draw from the alleged facts. *Id*. at 323-24. "Courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Id*. at 322-23. The plaintiff may not benefit from inferences flowing from vague or unspecific allegations. A complaint that fails to meet these requirements will be dismissed. *A&P*, 103 F. App'x at 468.

III. DISCUSSION

The Defendants move to dismiss Plaintiffs' Second Amended Complaint based on three arguments: (1) the new complaint relies on the same arguments about p-values and subgroups that were previously rejected by the Court; (2) the new allegations do not support a strong interference of scienter; and (3) Plaintiffs' remaining allegations are irrelevant and amount to a motion for reconsideration by Plaintiffs.[10] In response, Plaintiffs make two arguments. First, Plaintiffs argue that the Second Amended Complaint does not allege that Defendants knew rejection by the FDA was assured, but, rather, the Defendants were aware of material risks regarding the Prochieve NDA and failed to disclose those risks to investors. Second, Plaintiffs argue that the addition of the Devoe allegations, along with the rest of the material alleged in the Second Amended Complaint, support a strong inference of scienter for the Defendants. The Court addresses Plaintiffs' new allegations and the issue of scienter below.

a. The Devoe Allegations

Plaintiffs' Second Amended Complaint alleges that a district sales manager in Watson's Women's Health Division (Mr. Devoe) learned in July 2011 that Prochieve "wasn't going to be approved." (2d Am. Compl. ¶ 8.) They also allege that Watson's senior managers "were already talking about what [they] were going to do" because of the "likely failure" of the Prochieve NDA at that time. (2d Am. Compl. ¶ 8; *see also id*. ¶¶ 59, 128, 130, 132, 135, 151.)

Columbia makes two arguments as to why this new allegation does not assist Plaintiffs. First, Columbia argues that the allegations lack the requisite specificity required by the PSLRA because the Second Amended Complaint does not supply the "who, what, where, when, and

[10] The Watson Defendants also argue that Plaintiffs fail to allege an actionable misstatement or omission of material fact and fail to allege that the Watson statements caused Plaintiffs' losses. Because the Court dismisses for a failure to sufficiently plead facts supporting a strong inference of scienter, the Court declines to address these arguments.

how" that would give rise to a strong inference that Defendants acted with the required scienter. Second, Columbia argues that even if the Court credits the Devoe allegations, there is nothing that connects those allegations to the Columbia Defendants. Watson echoes Columbia's first argument and argues that the Devoe allegations occurred after all of Watson's alleged fraudulent communications took place, making the allegations irrelevant to Watson's scienter at the time of the alleged misstatements. In response Plaintiffs argue that it is highly unlikely that Watson would be aware of an impending rejection while Columbia was not due to their joint funding and work on the Prochieve NDA.

There is no dispute that the PSLRA requires that, with respect to each act or omission alleged to violate the PSLRA, the complaint shall state with particularity the facts (*i.e.*, the who, what, where, when, and how) giving rise to a strong inference that the defendant acted with the required state of mind or scienter. *Avaya*, 564 F.3d at 252-53; *A&P*, 103 F. App'x at 468-69. In one sense, the Devoe allegations provide the who (Devoe), the what (alleged statements by Watson "senior managers" in July 2011 that Prochieve "wasn't going to be approved"), the when (July 2011), and the where (Watson's Women's Health Division) for those allegations. But the allegations are missing the why and how required by the PSLRA.[11] The Second Amended Complaint does not provide any substance as to why the "senior managers" said Prochieve was not going to be approved or how the "senior managers" would know such information. This undermines the impact of the Devoe allegations. *Avaya*, 564 F.3d at 268 ("Omissions and ambiguities count against inferring scienter." (internal quotation marks omitted)).[12] In addition, Plaintiffs provide no connection between the Devoe allegations and the allegedly misleading

[11] In addition, the allegations are vague as to who the Watson "senior managers" are.

[12] The Court is mindful that it is to view the allegations holistically and not on an allegation by allegation basis. *See Tellabs*, 551 U.S. at 326.

statements. *See Kennilworth Partners L.P. v. Cendant Corp.*, 59 F. Supp. 2d 417, 430 (D.N.J. 1999) ("Most importantly, the plaintiffs do not sufficiently link the defendants, directly and specifically, with incidents or circumstances which, apart from their positions or roles within the various companies, connect them to wrongdoing and create a 'strong inference' of scienter.") Nor is there a connection between the Devoe allegations and other the reasons Plaintiffs give for why the statements were misleading (*i.e.*, Study 302 did not display statistical significance at the 99% confidence interval (p-value ≤ 0.01) "required" by the FDA; Study 302 did not achieve statistical significance at the 95% confidence interval in the U.S. subgroup; and Study 302 only achieved a 95% confidence interval by including "highly discrepant" data from test sites in Belarus and South Africa (2d Am. Compl. ¶ 104)).

Even taken at face-value, the Devoe allegations do not add any appreciable weight to Plaintiffs' scienter allegations with respect to the Columbia Defendants. There is nothing in the Second Amended Complaint that connects the Devoe allegations to the Columbia Defendants. Plaintiffs did allege that "[t]here is little doubt that as the recipient of the June 28 Letter [from the FDA], as well as the named sponsor of the NDA, the Columbia Individual Defendants were equally aware of the same information which led Watson to conclude that the NDA was likely to be rejected." (2d Am. Compl. ¶ 146.) But this allegation is conclusory and not supported by any factual particulars (*i.e.*, the who, what, when, where, and how). Moreover, these types of group allegations do not contribute to a strong inference of scienter. *See GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 245-46 (3d Cir. 2004) (finding that an allegation that a defendant "must have known" a statement was false or misleading due to a relationship with a co-defendant was insufficient to raise a strong inference for scienter purposes).

Similarly, the Devoe allegations do now show a strong inference of scienter for the Watson Defendants. Critically, the only statements by Watson alleged to be misleading occurred prior to July 2011. The Devoe allegations, taken as true, fail to impugn Watson's statements because the Devoe allegations took place in July 2011 and all of the alleged misstatements by Watson occurred prior to that time.

b. The Other New Allegations

The balance of Plaintiffs' new allegations are nothing but conclusory statements and legal conclusions.[13] When considering a motion to dismiss, the Court "may disregard any legal conclusions" and "conclusory" allegations. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009) (internal citations and quotations omitted). "A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). These new allegations are no more than re-argument attempting to undermine the Court's prior Opinion rather than factual allegations. As such, they do not help Plaintiffs create a strong inference for scienter.

c. No Strong Inference of Scienter

Plaintiffs' fraud allegations relate to a series of statements made by the Defendants between December 6, 2010 and January 20, 2012. Plaintiffs provide three reasons for why the statements are allegedly misleading: (1) Study 302 did not display statistical significance at the 99% confidence interval (p-value ≤ 0.01) "required" by the FDA; (2) Study 302 did not achieve

[13] *I.e.*, Stating that the following events do not indicate that the FDA found the Study 302 results to be sufficient for approval: the FDA's approval of a statistical analysis plan ("SAP") for Study 302 at a February 2011 meeting with Columbia (2d Am. Compl. ¶ 54); the FDA's acceptance of the Prochieve NDA filing (2d Am. Compl. ¶ 56); the FDA's decision to convene an Advisory Panel (2d Am. Compl. ¶ 62); and the acceptance of Study 302 in a medical journal (2d Am. Compl. ¶ 133). Notably these facts support the inference that Study 302 was not so fundamentally flawed as to make the application highly likely to fail.

statistical significance at the 95% confidence interval in the U.S. subgroup; and (3) Study 302 only achieved a 95% confidence interval by including "highly discrepant" data from test sites in Belarus and South Africa. (2d Am. Compl. ¶ 104.) These allegations remain unchanged from Plaintiffs' Amended Complaint. (*Compare* Am. Compl. ¶ 96 *with* 2d Am. Compl. ¶ 104.) For statements after June 28, 2011, Plaintiffs' claims also rely on the new Devoe allegations.

Taking the alleged facts in the Second Amended Complaint as a whole, the inference of scienter is not at least as compelling as any opposing non-fraudulent inference one could draw. The Second Amended Complaint still does not allege cogent facts showing that Defendants knew a p-value of 0.01 was "required" for Study 302.[14] Plaintiffs still rely on allegations that the FDA communicated such a requirement for Study 300 in 2004—years prior to Study 302. The Second Amended Complaint does not assert that the FDA specifically indicated a p-value requirement for Study 302. Furthermore, while Plaintiffs still allege facts about what was communicated during the Panel meeting regarding the p-value for Study 302, these allegations still do not adequately show that Defendants knew during the *earlier* Class Period that failing to achieve a p-value of 0.01 would likely be fatal for the NDA.

[14] Plaintiffs' new allegation that "'statistical significance' is the generally accepted standard for demonstrating efficacy, [but] the FDA requires a 'statistically very persuasive finding' when a single study trial is submitted in support of an NDA" (2d Am. Compl. ¶ 50) does not change the fact there is no allegation that a required p-value of 0.01 for Study 302 was communicated to Defendants. This amendment merely states that the results should be "statistically very persuasive." There is nothing indicating that a p-value of 0.022 does not meet this requirement. This is further supported by the fact that there is no allegation that the statistical analysis plan mentioned a confidence interval, the FDA's acceptance of the NDA, the lack of any mention of the p-value in the June 28, 2011 letter from the FDA, the FDA's commissioning of the Advisory Panel, and nearly 25% of the Advisory Panel voting in favor of approving the NDA.

Plaintiffs argue that the Second Amended Complaint alleges that Defendants knew of specific and material risks to the NDA and failed to disclose those risks to inventors.[15] These allegations rest on the same three pillars as the Amended Complaint.[16] But Plaintiffs' reframing of their allegations does not save the Second Amended Complaint.[17] The Court finds that the facts in the Second Amended Complaint collectively still do not create a strong inference that Defendants acted with an intent to deceive, manipulate or defraud, nor that their statements involved conscious misbehavior or "an extreme departure from the standards of ordinary care" that presented a danger of misleading investors that they knew or was so obvious that they must have been aware of it. *City of Roseville*, 442 F. App'x at 674-75.[18] As additional support for

[15] Plaintiffs make much out of the fact the Court's Order dismissing the First Amended Complaint stated that the allegations did not adequately show Defendants knew a lower p-value "would be fatal for the NDA." But whether Plaintiffs' fraud theory is presented as Defendants knew rejection was assured or that Defendants were aware of material risks regarding rejection (and failed to disclose those risks) makes no difference. Plaintiffs still must properly plead scienter—that is, the alleged facts, taken collectively must create an inference of scienter that is cogent and at least as compelling as any opposing inference of non-fraudulent intent one could rationally draw from the alleged facts. *Tellabs*, 551 U.S. at 323-24. Notably, the complaint, not attorney argument, defines the allegations of fraud. In any event, Plaintiffs' complaint still relies on the same reasons for *why* the statements are allegedly misleading (with the addition of the Devoe allegations for the statements made after June 28, 2011). The Plaintiffs' arguments reframing the allegations do not change this fact.

[16] As noted above, Plaintiffs also rely on the Devoe allegations. But for the reasons explained above, these allegations do not significantly change the Court's overall calculus as to the Defendants.

[17] The Court notes that much of Plaintiffs' Second Amended Complaint and Opposition states that the three elements Plaintiffs rely on to show misrepresentation were "required," contrary to its new argument that there was only a high risk of failure of the NDA rather than certain failure. (*See, e.g.*, 2d Am. Compl. ¶¶ 53, 65, 66, 68, 79, 80; Pl. Br. at 1, 2, 31, 37.) Plaintiffs' allegations are not internally consistent.

[18] Plaintiffs also fail to assert a plausible motive or opportunity on the part of Defendants, and "while 'motive and opportunity' may 'no longer serve as an independent route to scienter,' 'they are to be considered along with all the other allegations in the complaint." *Rahman v. Kid Brands, Inc.*, Civ. No. 11-1624, 2012 WL 762311, at *23 (D.N.J. March 8, 2012) (quoting

this conclusion, the Court incorporates its reasoning from its prior Order by reference [Dkt. No. 73].[19] In light of all of these reasons, viewed as a whole, the Court find that the stronger inference is that the Defendants did not believe the NDA was likely to fail due to its p-value and subgroup results,[20] and that Defendants did not knowingly or recklessly mislead investors when discussing Study 302.

Therefore, because Plaintiffs have failed to adequately plead the scienter element of their claims sufficient to establish liability under Section 10(b) of the Exchange Act and Rule 10b-5, these claims are dismissed. Accordingly, Plaintiffs allegations of control person liability under Section 20(a) must be dismissed for lack of an underlying violation of the Exchange Act.

Avaya, 564 F.3d at 277-78). Plaintiffs do not allege why Defendants would make any disclosure (or omission) to mislead or deceive investors. The argument that the Defendants would take any chance of success, no matter how small, is unlikely especially considering the substantial sums the Columbia and Watson defendants lost as a result of the FDA's denial of the NDA. (Dkt. No. 77-2 at 13 n.8; Dkt. No. 78-1 at 7 (Watson lost $19.2 million after the FDA Advisory Panel vote).) These losses and lack of motive weigh against a strong inference of scienter.

[19] *E.g.*, the FDA's acceptance of the NDA filing for Prochieve, the FDA's decision to convene an Advisory Panel, the FDA and Columbia Defendants agreement with respect to the Statistical Analysis Plan to ensure that variations in results across sites did not indicate localized data problems, the Defendants' continued investment in Prochieve and the NDA, the absence of an explicit p-value requirement for Study 302, the publication of Study 302 in a professional journal, and the four Panel votes in favor of approval of the NDA.

[20] Plaintiffs' reliance on *In re Amylin Pharms., Inc. Secs. Litig.*, 2003 U.S. Dist. LEXIS 7667 (S.D. Cal. May 1, 2003) and *In re Nuvelo, Inc. Sec. Litig.*, 668 F. Supp. 2d 1217 (N.D. Cal. 2009) is misplaced. *Amylin* involved statements that were contrary to statements by the FDA and contradicted by the collected data. Similarly, in *Nuvelo*, the complaint alleged that the defendant agreed to an ultra-law p-value with the FDA. In contrast, here, there is no allegation that the FDA communicated the necessity for a 0.01 p-value for Study 302.

IV. CONCLUSION & ORDER

For the reasons set forth above, the Court grants Defendants' Motions to Dismiss [Dkt. Nos. 77 & 78]. An appropriate Order will issue.

/s/ Faith S. Hochberg
Hon. Faith S. Hochberg, U.S.D.J.